

IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-1015 (GBW)
SAREPTA THERAPEUTICS, INC.,	)	
Defendant.	)	
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SAREPTA THERAPEUTICS, INC.,	)	
Defendant and Counter-Plaintiff	)	[REDACTED]
	)	
v.	)	
NIPPON SHINYAKU CO., LTD. and	)	
NS PHARMA, INC., Plaintiff and Counter-	)	
Defendants.	)	

**LETTER TO THE HONORABLE GREGORY B. WILLIAMS FROM NIPPON  
SHINYAKU CO. AND NS PHARMA, INC. REGARDING REQUEST FOR LEAVE  
TO FILE AN AMENDED ANSWER TO SAREPTA'S COUNTERCLAIMS**

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*Attorneys for Plaintiff/Counterclaim Defendant  
Nippon Shinyaku Co., Ltd. and Counterclaim  
Defendant NS Pharma, Inc.*

Dated: April 3, 2023

Dear Judge Williams:

Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. (collectively, “NS”) submit this reply in support of its motion for leave to file an Amended Answer and New Counterclaims (D.I. 177).

**NS’s Inequitable Conduct Claim is not Futile**

In its opposing letter (D.I. 183) Sarepta conflates written description with inventorship. “Conception is the touchstone of invention, and it requires a definite and permanent idea of an operative invention, including **every feature** of the subject matter sought to be patented.” *In re VerHoef*, 888 F.3d 1362, 1366 (Fed. Cir. 2018) (citations omitted). NS alleges that as of the priority date, [REDACTED] acknowledged the unpredictability of ASO design and [REDACTED]

[REDACTED] . D.I. 177-1 ¶¶ 50, 52, 55-59. This is insufficient for conception. *In re Curtis*, 354 F.3d 1347, 1358 (Fed. Cir. 2004) (There is no conception of a genus “by virtue of having disclosed a single species when . . . the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed.”).

Sarepta incorrectly suggests that a false claim of priority cannot make out an inequitable conduct as a matter of law. Not so. Inequitable conduct requires a misrepresentation or omission of material information, and specific intent to deceive the PTO. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (en banc). A priority claim is inherently material to patentability—it defines the universe of prior art and therefore may determine validity. *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1233 (Fed. Cir. 2007). Accordingly, inequitable conduct occurs where, as here, “the applicant [makes] an invalid priority claim to overcome an intervening reference.” *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1367 (Fed. Cir. 2001). The Sarepta-cited *CFL* opinion merely explains that under *Therasense* it is not enough that the patentee “could have relied on” the earlier priority—there must be some need to claim that priority date. *CFL Techs. LLC v. Osram Sylvania, Inc.*, No. 1:18-cv-01445-RGA, 2019 WL 2995815, at \*7 (D. Del. July 9, 2019). Here, NS alleges that [REDACTED] not only knew of intervening prior art which would have been but-for material to patentability, but also overcame an obviousness rejection by relying on the date of the invention to show unpredictability. D.I. 177-1 ¶¶ 80-87.

The other cases Sarepta relies on are readily distinguishable. In *Impact Engine* and *Novozymes*, the patent challenger failed to identify any specific misrepresentation to the PTO. *Impact Engine, Inc. v. Google, LLC*, No. 3:19-cv-01301, 2020 WL 3414627, at \*2 (S.D. Cal. June 22, 2020); *Novozymes A/S v. Danisco A/S*, No. 10-cv-251, 2011 WL 13210084, at \*12 (W.D. Wis. July 7, 2011). In contrast, NS identifies several statements [REDACTED] and their attorneys made during prosecution affirmatively misrepresenting **the time of the invention**. D.I. 177-1 ¶¶ 51-53. Accordingly, NS’s inequitable conduct claim is not futile as a matter of law or otherwise.

**NS’s Inequitable Conduct Claim Meets the Rule 9 Pleading Standard**

Sarepta apparently concedes that NS has adequately plead the “when, where, and how.” Further, NS has adequately identified the “who” ([REDACTED] and attorneys) and the “what” (statements made during prosecution). D.I. 177-1 ¶¶ 42-44, 51-53, 56-58, 61-62. NS did not “broadly cast a net” of individuals—it identified by name the specific individuals involved. *Id.* ¶¶ 42-44, 51-53. NS alleges that [REDACTED]

[REDACTED] —a fact [REDACTED] are uniquely situated to know. *Id.* ¶¶

56-58, 61-62. During prosecution [REDACTED] made representations about the unpredictability of art **at the time of the invention** to overcome obviousness rejections. *Id.* ¶¶ 51-53. Moreover, [REDACTED] knew of the additional Watanabe and Sazani intervening references—as Sarepta admits, [REDACTED] submitted them to the USPTO in an information disclosure statement (signed by prosecuting attorney [REDACTED]). But of course, the USPTO did not consider those references' bearing on patentability because [REDACTED] **misrepresented the time of invention as 2005.** *See Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 343 F. Supp. 2d 272, 310 (D. Del. 2004) (examiners first determine if a reference is prior art); D.I. 177-1 ¶¶ 51-53, 87. Accordingly, the proposed Amended Answer identifies “specific individual[s] [who] both knew of the invalidating information and had a specific intent to deceive the PTO.” *Senju Pharm. Co., Ltd. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 307 (D. Del. 2013). These allegations provide a reasonable inference of intent to deceive and satisfy the *Exergen* scienter requirement. *See Wyeth Holdings Corp. v. Sandoz*, No. 09-955-LPS-CJB, 2012 WL 600715, at \*7 (D. Del. Feb. 3, 2012) (dismissal is rarely appropriate “at the pleading stage due to the failure to adequately allege scienter”).

#### **NS's Proposed Walker Process Claim is Not Futile**

Sarepta alleges that NS makes “conclusory” allegations of Sarepta’s anticompetitive conduct. But NS has alleged facts showing the relevant product market, that there are no reasonable substitutes for ASO therapy, and that it has suffered a substantial antitrust injury. *See* D.I. 178; D.I. 177-1 ¶¶ 97, 101-102, 105-107. These factual allegations are anything but “threadbare recitals” of the elements of a *Walker Process* claim. *See TransWeb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1312 (Fed. Cir. 2016).

Sarepta’s arguments that it is entitled to *Noerr-Pennington* immunity are misguided. *Noerr-Pennington* precludes antitrust liability for merely bringing a lawsuit. *Tyco Healthcare Grp. LP v. Mutual Pharm. Co.*, 762 F.3d 1338, 1343 (Fed. Cir. 2014). The Federal and Third Circuits recognize *Walker Process* fraud and sham litigation as two distinct exceptions to that immunity. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071-72 (Fed. Cir. 1998); *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 266 (3d Cir. 2017). Unlike the sham litigation exception—which NS has not raised—*Walker Process* fraud does not require the claim be objectively baseless. *Nobelpharma*, 141 F.3d at 1071. Because Sarepta knowingly asserted patents obtained by fraud on the PTO, Sarepta is not entitled to *Noerr-Pennington* immunity.

#### **NS's Proposed Amended Answer is Timely and Sarepta Will Suffer No Undue Prejudice**

NS’s motion is timely. NS requested leave within the deadline for filing an amended pleading.<sup>1</sup> Moreover, Sarepta only produced [REDACTED] establishing lack of conception in late January. There are still four months left in fact discovery and there is substantial overlap in NS’ proposed claims and the pending claims. Thus, amendment will cause Sarepta no undue prejudice. *See Micron Tech., Inc. v. Rambus Inc.*, 409 F. Supp. 2d 552, 559 (D. Del. 2006).

\* \* \*

NS’s proposed Amended Answer is timely and not futile. NS therefore respectfully requests the Court grant its Motion for leave to file an Amended Answer.

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<sup>1</sup> Sarepta moved to add UWA as a counterclaim plaintiff two days before this deadline even though it licensed the patents from UWA in 2008 and thus knew for years that UWA is the patent owner.

April 3, 2023

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